

**REMARKS****Status of Claims**

Claims 1-5, 8-24, 44, 47-53 and 55-74 were pending at the time of the Office Action. Claims 5, 53 and 58 are cancelled herein without prejudice. Claims 1-4, 8, 10-17, 23-24, 44, 47-48, 50-52, 55-57, 60, 62-69 and 73-74 are currently amended. Claims 9, 18-22 and 49 were originally presented; and claims 59, 61 and 70-72 were previously presented. Claims 75-78 are new. Accordingly, by this amendment, claims 1-4, 8-24, 44, 47-52, 55-57 and 59-78 remain pending in the application.

**Rejections under § 102**

The Office Action rejected claims 1-3, 8-10, 13-17, 19-20, 22, 44, 47-50, 55-57, 59-62, 65-69 and 71-72 under 35 U.S.C. § 102(e) as being anticipated by Sherry, U.S. Patent No. 6,358,238. These rejections are respectfully traversed with respect to independent claims 1, 47 and 55, as amended herein.

In order to better differentiate Applicant's claims from the teaching of Sherry, Applicant has amended claim 1 to recite that "the layer and the barrier layer are configured to define a tubular structure" and that "the barrier layer is configured to provide a barrier to the diffusion of CO<sub>2</sub>." This configuration of the barrier layer serves one of the problems posed by the Applicant, the problem being that diffusion of CO<sub>2</sub> through the walls of a catheter may lead to precipitation and ultimately to the formation of obstructions. The gas permeability index of PTFE Teflon for CO<sub>2</sub> is much lower than that of other materials commonly used to produce catheter walls. Thus, by using a barrier layer comprised of, for example, PTFE Teflon, the diffusion of CO<sub>2</sub> into the lumen of the catheter is substantially hindered.

In contrast, Sherry does not disclose configuring a barrier layer to provide a barrier to the diffusion of CO<sub>2</sub>. The text cited in the Office Action (col. 5, lines 18-19 and 21-22) discloses that the inner layer 34 preferably comprises a lubricious polymer such as PTFE. At most, Sherry describes the lubricious quality of PTFE. However, Sherry does not describe or suggest the gas permeability of PTFE Teflon with respect to CO<sub>2</sub>. Furthermore, Sherry does not describe or

suggest the gas permeability of PTFE Teflon with respect to CO<sub>2</sub> relative to that of other materials commonly used to produce catheter walls. As a result, Sherry does not teach using a barrier layer comprised of PTFE Teflon to substantially hinder the diffusion of CO<sub>2</sub> into the lumen of the catheter. Furthermore, Sherry does not describe or suggest a barrier layer “configured to provide a barrier to the diffusion of CO<sub>2</sub>”. At least because of the noted reasons, it is believed that claim 1 is not anticipated by Sherry under § 102(e).

At least by virtue of their dependency from claim 1, it is believed that claims 2-3, 8-10, 13-17, 19-20 and 22, claim 44 (amended herein to depend from claim 22), and new claims 75-76 also are not anticipated by Sherry under § 102(e). Furthermore, claim 20 has been amended to recite that “an inner diameter of the distal end has a flared shape having a wider end, the wider end located at the distal end.” Sherry discloses that the inner diameter of the distal end 18 has a tapered shape having a narrow end located at the distal end (see Fig. 2). Upon applying pressure within the catheter, the inner diameter expands such that the inner diameter at the distal end is equal to the inner diameter of the shaft portion 16 (see Figs. 4A and 4B). The teachings of Sherry are distinguishable from Applicant’s invention in which the inner diameter of the lumen 36 at the distal tip 33 is larger than the inner diameter of the lumen 36 at the apex 38 (see Fig. 3). Because of the noted reasons, it is further believed that claim 20 and claim 21 (at least by virtue of its dependency from claim 20) are not anticipated by Sherry under § 102(e).

Furthermore, claim 75 recites that “the tubular structure is configured to inhibit expansion due to pressure within the tubular structure.” The tubular structure is able to inhibit this expansion because the barrier layer comprises a relatively stiff, dense material (see page 9, lines 27-28 in the specification). The stiffness may facilitate the projection of the catheter through the body (see page 9, line 20 in the specification). The protrusion at the distal end of the outer layer beyond the barrier layer creates the aforementioned flared portion, which aids the expulsion of deposit formations. This flared portion is created by the protrusion and not by the application of pressure within the tubular structure. As explained above, the material forming the tubular structure is chosen to inhibit expansion due to pressure within the tubular structure.

In contrast, Sherry discloses that an end portion of a catheter shaft expands in diameter upon the application of pressure to the lumen of the catheter (see Abstract). The expandable

portion expands from a first diameter to a second diameter upon increasing the pressure in the lumen of the shaft (see Col. 2, lines 65-67). This expansion capability is provided by a reinforcement structure that includes a plurality of circumferential elements having means for permitting an increase in the circumference (see Col. 3, lines 6-10). Thus, the catheter in Sherry has a structure that expressly does not inhibit expansion due to pressure applied from within the catheter. Rather, Sherry discloses a structure that promotes such expansion. In this manner, Sherry teaches away from a catheter having a tubular structure that is configured to inhibit expansion due to pressure within the tubular structure. Because of the noted reasons, it is further believed that claim 75 is not anticipated by Sherry under § 102(e). Because Sherry does not describe or suggest composing a barrier layer of material having sufficient rigidity and density to inhibit expansion of the tubular structure due to pressure within the tubular structure, it is further believed that claim 76 is not anticipated by Sherry under § 102(e).

Just as Applicant has amended claim 1 to better differentiate this claim from the teaching of Sherry, Applicant has similarly amended claim 47 to recite that “the barrier layer is configured to provide a barrier to the diffusion of CO<sub>2</sub>.” Sherry does not disclose configuring a barrier layer to provide a barrier to the diffusion of CO<sub>2</sub>. Sherry describes the lubricious quality of PTFE, but it does not describe or suggest the gas permeability of PTFE Teflon with respect to CO<sub>2</sub>. Furthermore, Sherry does not describe or suggest this gas permeability of PTFE Teflon with respect to CO<sub>2</sub> relative to that of other materials commonly used to produce catheter walls. As a result, Sherry does not teach using a barrier layer comprised of PTFE Teflon to substantially hinder the diffusion of CO<sub>2</sub> into the lumen of the catheter. Furthermore, Sherry does not describe or suggest a barrier layer “configured to provide a barrier to the diffusion of CO<sub>2</sub>.” At least because of the noted reasons, it is believed that claim 47 is not anticipated by Sherry under § 102(e). At least by virtue of their dependency from claim 47, it is believed that claims 48-50 are not anticipated by Sherry under § 102(e).

Just as Applicant has amended claim 1 to better differentiate this claim from the teaching of Sherry, Applicant has similarly amended claim 55 to recite that “the barrier layer is configured to provide a barrier to the diffusion of phenolic compounds.” Sherry does not disclose configuring a barrier layer to provide a barrier to the diffusion of phenolic compounds. Sherry

describes the lubricious quality of PTFE, but it does not describe or suggest the gas permeability of PTFE Teflon with respect to phenolic compounds. Furthermore, Sherry does not describe or suggest this gas permeability of PTFE Teflon with respect to phenolic compounds relative to that of other materials commonly used to produce catheter walls. As a result, Sherry does not teach using a barrier layer comprised of PTFE Teflon to substantially hinder the diffusion of phenolic compounds into or out of the lumen of the catheter. Furthermore, Sherry does not describe or suggest a barrier layer “configured to provide a barrier to the diffusion of phenolic compounds”. At least because of the noted reasons, it is believed that claim 55 is not anticipated by Sherry under § 102(e).

At least by virtue of their dependency from claim 55, it is believed that claims 56-57, 59-62, 65-69 and 71-72 and new claims 77-78 also are not anticipated by Sherry under § 102(e). Furthermore, claim 77 recites that “the tubular structure is configured to inhibit expansion due to pressure within the tubular structure.” As explained with respect to claim 75, the tubular structure is able to inhibit this expansion because the barrier layer comprises a relatively stiff, dense material. In contrast, Sherry discloses that an end portion of a catheter shaft expands in diameter upon the application of pressure to the lumen of the catheter. Thus, the catheter in Sherry has a structure that expressly does not inhibit expansion due to pressure applied from within the catheter. In this manner, Sherry teaches away from a catheter having a tubular structure that is configured to inhibit expansion due to pressure within the tubular structure. Because of the noted reasons, it is further believed that claim 77 is not anticipated by Sherry under § 102(e). Because Sherry does not describe or suggest composing a barrier layer of material having sufficient rigidity and density to inhibit expansion of the tubular structure due to pressure within the tubular structure, it is further believed that claim 78 is not anticipated by Sherry under § 102(e).

The Office Action rejected claims 1, 3-4, 11-14, 17, 19, 22-24, 44, 47, 51-52, 55-56, 59, 63-66, 69 and 71-74 under 35 U.S.C. § 102(e) as being anticipated by Barry et al., U.S. Patent No. 6,663,606. These rejections are respectfully traversed with respect to independent claims 1, 47 and 55, as amended herein.

As explained earlier, claim 1 has been amended to recite that “the barrier layer is configured to provide a barrier to the diffusion of CO<sub>2</sub>.” In contrast, Barry addresses a medical device having a metallic or polymeric component that comes into contact with a pharmaceutically active material (see Col. 3, lines 1-4). The contact between the component and the material reduces the pharmaceutical effectiveness of the material (see Col. 3, lines 5-6). To overcome this incompatibility between the component and the material, Barry teaches modifying the component by providing a surface treatment (see Col. 3, lines 33-35) or replacing it with a more compatible metallic or polymeric component (see Col. 3, lines 59-61). This teaching does not describe or suggest using a barrier layer configured to provide a barrier to the diffusion of CO<sub>2</sub>. At least because Barry does not teach the noted feature, it is believed that claim 1 is not anticipated by Barry under § 102(e). At least by virtue of their dependency from claim 1, it is believed that claims 3-4, 11-14, 17, 19, 22-24 and 44 and new claims 75-76 also are not anticipated by Barry under § 102(e). Because Barry does not describe or suggest that “an inner diameter of the distal end has a flared shape having a wider end, the wider end located at the distal end,” it is further believed that claims 20 and 21 are not anticipated by Barry under § 102(e). Because Barry does not describe or suggest that “the tubular structure is configured to inhibit expansion due to pressure within the tubular structure,” it is further believed that claim 75 is not anticipated by Barry under § 102(e). Because Barry does not describe or suggest composing a barrier layer of a material having sufficient rigidity and density to inhibit expansion of the tubular structure due to pressure within the tubular structure, it is further believed that claim 76 is not anticipated by Sherry under § 102(e).

As explained earlier, claim 47 has been amended to recite that “the barrier layer is configured to provide a barrier to the diffusion of CO<sub>2</sub>.” The teaching in Barry does not describe or suggest using a barrier layer configured to provide a barrier to the diffusion of CO<sub>2</sub>. At least because Barry does not teach the noted feature, it is believed that claim 47 is not anticipated by Barry under § 102(e). At least by virtue of their dependency from claim 47, it is believed that claims 51-52 also are not anticipated by Barry under § 102(e).

As explained earlier, claim 55 has been amended to recite that “the barrier layer is configured to provide a barrier to the diffusion of phenolic compounds.” Just as Barry does not

describe or suggest using a barrier layer configured to provide a barrier to the diffusion of CO<sub>2</sub>, Barry does not describe or suggest using a barrier layer configured to provide a barrier to the diffusion of phenolic compounds. At least because Barry does not teach the noted feature, it is believed that claim 55 is not anticipated by Barry under § 102(e). At least by virtue of their dependency from claim 55, it is believed that claims 56, 59, 63-66, 69 and 71-74 and new claims 77-78 also are not anticipated by Barry under § 102(e). Because Barry does not describe or suggest that “the tubular structure is configured to inhibit expansion due to pressure within the tubular structure,” it is further believed that claim 77 is not anticipated by Barry under § 102(e). Because Barry does not describe or suggest composing a barrier layer of material having sufficient rigidity and density to inhibit expansion of the tubular structure due to pressure within the tubular structure, it is further believed that claim 78 is not anticipated by Barry under § 102(e).

### **Rejections under § 103**

The Office Action rejected claims 18 and 70 under 35 U.S.C. § 103(a) as being unpatentable over Sherry in view of Bardsley et al., U.S. Patent No. 6,004,310. Claim 18 depends from claim 1, which recites that “the barrier layer is configured to provide a barrier to the diffusion of CO<sub>2</sub>.” At least because Bardsley does not teach the noted feature that is missing from Sherry, it is believed that claim 18 is patentable over Bardsley and Sherry.

Claim 70 depends from claim 55, which recites that “the barrier layer is configured to provide a barrier to the diffusion of phenolic compounds.” At least because Bardsley does not teach the noted feature that is missing from Sherry, it is believed that claim 70 is patentable over Bardsley and Sherry.

The Office Action rejected claim 21 under 35 U.S.C. § 103(a) as being unpatentable over Sherry in view of Nita et al., U.S. Patent No. 5,916,192. Claim 21 depends from claim 1, which recites that “the barrier layer is configured to provide a barrier to the diffusion of CO<sub>2</sub>.” At least because Nita does not teach the noted feature that is missing from Sherry, it is believed that claim 21 is patentable over Nita and Sherry.

**Conclusion**

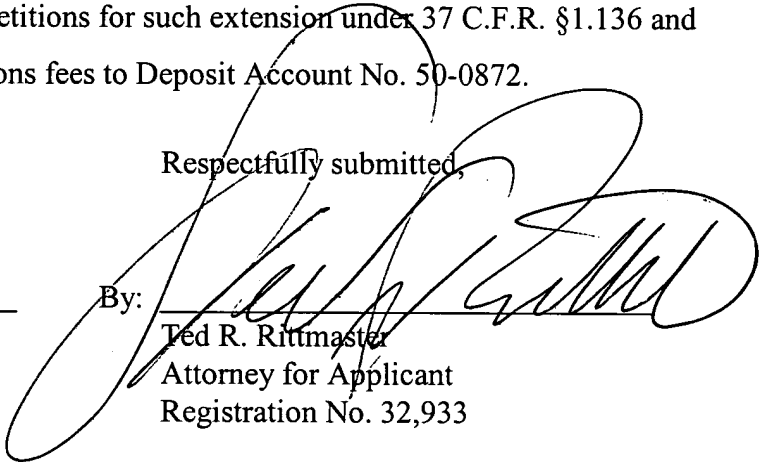
Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 50-0872.

Respectfully submitted,

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